

EXHIBIT 9

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SKYROCKETING PRESCRIPTION DRUG PRICES

HEARINGS

BEFORE THE

SPECIAL COMMITTEE ON AGING UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

WASHINGTON, DC

ARE WE GETTING OUR MONEY'S WORTH?
JULY 18, 1989

TURNING A BAD DEAL INTO A GOOD DEAL
NOVEMBER 16, 1989

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TURNING A BAD DEAL INTO A GOOD DEAL

NOVEMBER 16, 1989

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(III)

PRESCRIPTION DRUG PRICES: ARE WE GETTING OUR MONEY'S WORTH?

TUESDAY, JULY 18, 1989

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 9:38 a.m., in room 628, Dirksen Senate Office Building, Hon. David Pryor (chairman of the committee) presiding.

Present: Senators Pryor, Shelby, Reid, Graham, Kohl, Cohen, Pressler, Grassley, Wilson, Simpson, Warner, and Kassebaum.

Staff present: Portia Porter Mittelman, staff director; Christopher C. Jennings, deputy staff director; David Schulke, chief of oversight; and John Monahan, investigator.

OPENING STATEMENT BY SENATOR DAVID PRYOR, CHAIRMAN

The CHAIRMAN. Good morning, ladies and gentlemen. This morning we begin a series of hearings that will explore three questions: One, what is the value of the prescription drug products we buy? Two, what are the benefits of these drugs as compared to their costs? And three, what can we do to make certain that we are paying a fair price? From the tiniest baby in America to the oldest citizen in our country, it is an issue that affects all of us.

First, I must say I'm sorely disappointed that we will be unable to adequately pose and ultimately answer these questions this morning because those companies that manufacture these drugs chose not to come to this hearing. They chose not to testify today even though we changed the timing of this hearing to accommodate the conflict of schedules of company spokespersons. They should, it would appear, want to be present to make themselves available to be a part of this dialog.

Many of these companies who proclaim the benefits their drugs produce evidently refuse in public to talk about the profits that they reap. When it comes to boasting of their profits to Wall Street, the drug companies can be heard loud and clear, but they are awfully quiet when it comes to discussing the prices they charge on Main Street.

Only one of the 18 drug manufacturers that was invited is present today. Those invited today who are not here include: American Home Products Corp., Barr Laboratories, Bolar Pharmaceutical, Eli Lilly and Co., Geneva Generics, Inc., Glaxo, Inc., Marion Laboratories, Inc., Merck Sharp and Dohme, Pfizer, Rugby-Darby Group Companies, Inc., Schein Pharmaceutical, Schering-Plough

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The CHAIRMAN. Mr. Laughrey, do you have any comments on that final line of questioning?

Mr. LAUGHREY. Well, the product in question was Motrin. It has lost its patent, it is now available as a multiple source product, so it didn't surprise me that in fact the VA hospitals could receive a \$5 price as opposed to the \$29 price that Medicare might pay. Single source items, it might be a little more difficult to negotiate those types of discounts given our retail pharmacists' distribution system.

The CHAIRMAN. Do you think that Medicare should attempt to negotiate with the vendors, just like the Veterans Administration has?

Mr. LAUGHREY. I think they should attempt to. Obviously, if we can save our taxpayers' money—

The CHAIRMAN. Watching trends in drug prices, would you have any faith or any reason to believe that the drug manufacturers would want to negotiate with Medicare, just as some of them might have with the Veterans Administration?

Mr. LAUGHREY. I would guess they would prefer not to negotiate.

The CHAIRMAN. Why?

Mr. LAUGHREY. I think they want to continue their level of profitability as they have in the past.

The CHAIRMAN. Which has been relatively or extremely high?

Mr. LAUGHREY. Well, that's a postulation again on my part. I'd say it's reasonably high.

The CHAIRMAN. OK, sir.

I want to thank both of you. You've been very constructive this morning, and again, very patient. And we're going to put your full statements in the record, and we'll perhaps be calling on you again for your expertise and your knowledge, and certainly your cooperation.

We have Mr. Louis Hays. Mr. Hays, we welcome you today. I don't know if you had to sit through all of this this morning, but we've had a very lively discussion on prescription drug prices, costs, value, et cetera. And we look forward to your statement. We're going to try to limit this statement to 5 minutes, and then I will have a few questions, not many. But we appreciate you coming, and appreciate your statement. The full body of your statement will be printed in the record.

**STATEMENT OF LOUIS B. HAYS, ACTING ADMINISTRATOR OF
HCFA, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Mr. HAYS. Thank you very much, Mr. Chairman. I am pleased to be here today to discuss the pricing of outpatient prescription drugs under the Medicare Program.

At the outset, let me reiterate that our estimates of the Medicare outpatient prescription drug program continue to show that the program is considerably underfunded. Over the first 4 years of the program, benefits are expected to exceed the premiums received by nearly \$800 million, and with administrative costs included, the shortfall rises to almost \$2.8 billion. I understand that the most recent Congressional Budget Office projections are consistent now with the administration's projections.

With respect to the drug pricing mechanism under the new drug program, the law is very specific with regard to Medicare payments for outpatient prescription drugs. After the annual deductible is met, Medicare will pay the lesser of the pharmacy's actual charge for the drug, or an applicable payment limit minus the required co-insurance amount. The payment limit depends on whether the drug is available from multiple sources, only a single source, or as a brand name drug specified in writing by the physician. The payment limit for most drugs will be average wholesale price of the drug. While the term "average wholesale price" is suggestive of the amount that pharmacies actually pay for drugs, it is in fact, significantly higher than actual costs. The average wholesale price is somewhat comparable to the manufacturer's sticker price on a new car.

Indeed, there have been a number of studies which indicate that published average wholesale price for drugs overstates the actual prices paid by as much as 10 to 20 percent, because of discounts, special offers, or purchasing incentives. Unlike the Medicaid Program, we have no authority to take advantage of these discounts under Medicare.

You specifically asked that I mention our decision on the newly approved drug, Epoetin, otherwise known as EPO. On June 1, the Food and Drug Administration approved Epoetin for the treatment of anemia associated with chronic renal failure. This drug is expensive, and since the Medicare Program pays the vast majority of expenses for end-stage renal disease patients, we held significant discussions with the company that received FDA approval for the drug, namely, Amgen Inc. Based on those discussions, which included examination of detailed cost data volunteered by Amgen, we set a reasonable price to pay kidney-dialysis facilities for the administration of this drug in conjunction with dialysis treatment. The price we announced is \$4,650 for each person receiving Epoetin. We plan to evaluate the price in 6 months, but we believe the price we set is reasonable for both dialysis facilities and the taxpayer.

The Department has been concerned with the cost of the outpatient prescription drug program since discussions of the benefit began over 2 years ago. In a May 1989 report to Congress we outlined the assumptions used in calculating the \$2.8 billion deficit in the drug trust fund. We estimate that Medicare beneficiaries who purchased prescriptions in 1988 purchased an average of 21.5 prescriptions in that year. By 1993, that figure will rise to 23.3 prescriptions. We also estimate that the average cost for outpatient prescription drugs will increase from \$18.21 in 1988 to \$24.26 by 1993. Finally, we assume an induced demand effect which could increase aggregate consumption of drugs by the Medicare population by about 10 percent in 1991, 12 percent in 1992, and 11 percent in 1993.

We are also preparing a report to Congress on drug prices and pharmacy charges as required by the catastrophic legislation. Allow me to describe briefly some of the trends that we will be mentioning in our report.⁹

⁹ See appendix 3 draft report to Congress on Manufacturers' Prices and Pharmacists' charges.

The producer price index measures prices received in commercial transactions by producers of various goods. In the case of the producer price index, or PPI, is a measure charged by drug manufacturers for drugs. In 1981 and 1986 the annual growth rate for drugs was 10.1 percent. In 1987 and 1988 the growth rate was 9.6 percent and 7.9 percent respectively. These rates have been noted in the growth of total drug costs as well.

In concluding my statement, Mr. Chairman, the catastrophic drug benefit represents a major challenge to the Medicare Program, and presents us with many challenges. As we proceed with implementation, we are concerned by the projected underfunding and the volatility of prescription drug costs. We look forward to working with this committee and Congress, to help ensure that the program is sound, and that it serves Medicare beneficiaries. I am happy to answer any questions that you may have.

[The prepared statement of Mr. Hay]

The producer price index measures the change over time in the prices received in commercial transactions by manufacturers and producers of various goods. In the case of prescription drugs, the producer price index, or PPI, is a measure of the change in prices charged by drug manufacturers for the drugs they sell. Between 1981 and 1986 the annual growth rate in the PPI for prescription drugs was 10.1 percent. In 1987 and 1988 the PPI moderated somewhat to 9.6 percent and 7.9 percent respectively. Similar trends have been noted in the growth of the consumer price index for drugs as well.

In concluding my statement, Mr. Chairman, I would note that the catastrophic drug benefit represents a major expansion of the Medicare Program, and presents us with enormous administrative challenges. As we proceed with implementation, on schedule, we are concerned by the projected underfunding of the drug trust fund and the volatility of prescription drug prices in recent years. We look forward to working with this committee, and the others in the Congress, to help ensure that the drug program is financially sound, and that it serves Medicare beneficiaries well. I would be happy to answer any questions that you might have, Mr. Chairman.

[The prepared statement of Mr. Hays follows:]

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STATEMENT OF LOUIS B. HAYS
 ACTING ADMINISTRATOR
 HEALTH CARE FINANCING ADMINISTRATION
 BEFORE
 THE SPECIAL COMMITTEE ON AGING
 UNITED STATES SENATE
 JULY 18, 1989

Good morning. I am pleased to be here today to discuss the pricing of outpatient prescription drugs under Medicare.

At the outset, I must reiterate, as stated in our May 1989 Report to Congress concerning the catastrophic outpatient drug program, that HCFA estimates of the Medicare outpatient drug program continue to show that the program is considerably underfunded. Over the first four years of the program (1990 - 1993), benefit payments are expected to exceed premiums received by nearly \$800 million. With administrative costs included, the shortfall rises to almost \$2.8 billion. I understand that the most recent Congressional Budget Office (CBO) projections are consistent with the Administration's projections. By the end of 1992, we project that there will be insufficient cash on hand in the Catastrophic Drug Insurance Trust Fund to pay claims, and some benefit payments will have to be deferred until additional premiums come in.

With the financial difficulty facing the drug trust fund as a sobering reminder of our responsibility to foster the drug program's viability, allow me to share with you an explanation of the new drug benefit and its financing mechanism, as well as information on the trends in prescription drug costs over the past several years.

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THE MEDICARE OUTPATIENT DRUG BENEFIT

The outpatient prescription drug program intended to help relieve the financial burden on beneficiaries by unusually high out-of-pocket bills. This new benefit represents a change in Medicare. Beginning in 1990, Medicare will cover immunosuppressive therapy and certain other drugs. In 1991, the benefit will expand to cover outpatient prescription drugs approved by the Food and Drug Administration (FDA).

After a beneficiary has satisfied an annual deductible, Medicare will pay its share of the cost of a prescription drug. The beneficiary will be responsible for the remaining coinsurance amount. With some exceptions, the coinsurance is 50 percent in 1991, 40 percent in 1992 and thereafter (providing the required Catastrophic Drug Insurance Trust Fund is available).

OUTPATIENT PRESCRIPTION DRUG PRICING UNDER MEDICARE

The law is very specific with regard to the pricing of outpatient prescription drugs. After a beneficiary has satisfied the deductible, Medicare will pay the lesser of the actual cost of the drug, or the applicable payment limit. The method Medicare uses for calculating payment limits is set in the law. I will use a detailed methodology, allow me to briefly describe it to give you a flavor for the very essence of the methodology. It is really a very simple methodology, little, if any, opportunity exists with it to encourage cost savings in the outpatient drug program.

The methodology for calculating Medicare payment limits depends on whether the drug is available from only a single source, or is a brand name drug. If a drug is written by the physician.

THE MEDICARE OUTPATIENT DRUG BENEFIT

The outpatient prescription drug program under Medicare is intended to help relieve the financial burden sometimes imposed on beneficiaries by unusually high outpatient prescription drug bills. This new benefit represents a significant expansion of Medicare. Beginning in 1990, Medicare will pay for drugs used in immunosuppressive therapy and certain home intravenous (IV) drugs. In 1991, the benefit will expand to include all other outpatient prescription drugs approved by the Food and Drug Administration (FDA).

After a beneficiary has satisfied an annual deductible, Medicare will pay its share of the cost of a particular drug, and the beneficiary will be responsible for the remainder, a so-called coinsurance amount. With some exceptions, the coinsurance amount is 80 percent in 1991, 40 percent in 1992, and 20 percent in 1993 and thereafter (providing the required contingency margin for the Catastrophic Drug Insurance Trust Fund is met).

OUTPATIENT PRESCRIPTION DRUG PRICING UNDER MEDICARE

The law is very specific with regard to Medicare payments for outpatient prescription drugs. After the annual deductible is met, Medicare will pay the lesser of the pharmacy's actual charge for the drug, or the applicable payment limit, minus the required coinsurance amount. The method Medicare must employ in calculating payment limits is set in law. While it is a rather detailed methodology, allow me to briefly mention key aspects of it to give you a flavor for the very explicit and inflexible nature of the methodology. It is readily apparent that very little, if any, opportunity exists within this payment framework to encourage cost savings in the outpatient drug program.

The methodology for calculating Medicare's payment for a drug depends on whether the drug is available from multiple sources, only a single source, or is a brand name drug specified in writing by the physician.

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For single source drugs and multiple source drugs with brand names prescribed: Prior to January 1, 1992, the payment limit is the number of units dispensed multiplied by the per unit average price for the drug, plus an administrative allowance. Beginning January 1, 1992, the payment limit is the lesser of the calculation specified above or the 90th percentile of the actual charge per unit computed on a geographic basis for the second previous calculation period, adjusted to reflect the number of units dispensed.

For multiple source drugs: The payment limit is the number of units dispensed multiplied by the average price per unit plus the administrative allowance.

To determine the average price of single source drugs, the Secretary is required to conduct a biannual survey of direct sellers, wholesalers, or pharmacies as appropriate. If the sales volume of a drug is so low that such a survey is not appropriate, or for other reasons, the Secretary may price the drug based only on the published average wholesale price.

To determine the average price of multiple source drugs, the Secretary may price the drug based on either the published average wholesale price or the biannual survey.

Even while I have spared you many of the details and nuances of the law, it is clear that HCFA has little room to innovate within this rigid payment system. Under current law, HCFA has no authority to negotiate more competitive prices or demand the discounts warranted by the large volume of business the Medicare program represents. Indeed, the statute requires us to exclude from the price survey the discounts which pharmacies typically receive from drug companies. Thus, the survey prices will overstate actual pharmacy costs. Multiple source drugs make up the lion's share of the prescription drug market, and, essentially, Medicare will pay the average wholesale price for these drugs. While the term "average wholesale price" is suggestive of the amount that pharmacies actually pay for drugs, it is significantly higher than actual costs. The average wholesale price is somewhat comparable to the manufacturer's "sticker price" on a new car -- this is rarely the price actually

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paid for the car. Indeed, there have been which indicate that the published average w drugs overstates actual prices paid by as m percent because of discounts, special offer incentives.

The states have had more than 20 years of e prescription drugs under the Medicaid progr employed creative and cost effective method drug costs without lowering the quality of the state of Maine pays the average wholesa percent, while both Tennessee and Ohio pay price minus 7.5 percent. To further illust pays the average wholesale price minus 9.5 ; pays the average wholesale price minus 10.5 reductions from the average wholesale price surveys, conducted by states, of dispensing acquisition costs for pharmacies.

EPOETIN

You specifically asked that I mention our d approved drug epoetin. On June 1, the FDA i the treatment of anemia associated with chro This drug is expensive -- some countries in \$9,000 to \$11,000 per year per patient for Medicare program pays the vast majority of Renal Disease (ESRD) patients, we held signi with the company that received FDA approval, on those discussions, which included the exa cost data volunteered by AMGEN, we set a rea kidney dialysis facilities for the administr conjunction with dialysis treatment. I shou data were easy to evaluate because epoetin i marketable product. The price we announced patient receiving epoetin. We must still se and payment rates outside dialysis facilitie evaluate the price in six months. We believ reasonable for both dialysis facilities and

paid for the car. Indeed, there have been a number of studies which indicate that the published average wholesale price for drugs overstates actual prices paid by as much as 10 to 20 percent because of discounts, special offers or purchasing incentives.

The states have had more than 20 years of experience paying for prescription drugs under the Medicaid program. Many states have employed creative and cost effective methods of limiting their drug costs without lowering the quality of care. For example, the state of Maine pays the average wholesale price minus 5 percent, while both Tennessee and Ohio pay the average wholesale price minus 7.5 percent. To further illustrate, South Carolina pays the average wholesale price minus 9.5 percent, and Texas pays the average wholesale price minus 10.5 percent. These reductions from the average wholesale price are usually based on surveys, conducted by states, of dispensing costs and actual acquisition costs for pharmacies.

EPOETIN

You specifically asked that I mention our decision on the newly approved drug epoetin. On June 1, the FDA approved epoetin for the treatment of anemia associated with chronic renal failure. This drug is expensive -- some countries in Europe are paying \$9,000 to \$11,000 per year per patient for this drug. Since the Medicare program pays the vast majority of expenses for End Stage Renal Disease (ESRD) patients, we held significant discussions with the company that received FDA approval, AMGEN, Inc. Based on those discussions, which included the examination of detailed cost data volunteered by AMGEN, we set a reasonable price to pay kidney dialysis facilities for the administration of this drug in conjunction with dialysis treatment. I should note that the cost data were easy to evaluate because epoetin is AMGEN's first marketable product. The price we announced is \$4,650 for each patient receiving epoetin. We must still set coverage guidelines and payment rates outside dialysis facilities, and we plan to evaluate the price in six months. We believe the price we set is reasonable for both dialysis facilities and the taxpayer.

REPORTS TO CONGRESS

The Department has been concerned with the projected cost of the outpatient prescription drug program since discussions of such a benefit began over two years ago. In a May 1989 Report to Congress entitled, "Expenses Incurred by Medicare Beneficiaries for Prescription Drugs", the Department outlined the assumptions used in calculating the estimated \$2.8 billion deficit in the drug trust fund. The Department estimates that Medicare beneficiaries who purchased prescriptions in 1988 purchased an average of 21.5 prescriptions in that year. By 1993, outpatient prescription drug users will purchase an average of 23.3 outpatient prescriptions. We also estimate that the cost per outpatient prescription drug will increase from \$18.21 in 1988 to \$24.26 by 1993.

Perhaps the most difficult element of the program's cost to estimate is that of induced demand. It is commonly acknowledged in the insurance industry that the very act of coverage tends to increase demand for the covered service. This insurance effect is called "induced demand." HCFA actuaries assume an insurance effect which would increase aggregate consumption of drugs by the Medicare population by about 10 percent in 1991, 12 percent in 1992, and 11 percent in 1993.

The Department is also preparing a report to Congress on drug manufacturers' prices and pharmacists' charges as required by the HCCA of 1988. Allow me to briefly describe some of the prescription drug industry trends we mention in our report.

The Producer Price Index (PPI) measures the change over time in the prices received in commercial transactions by manufacturers and producers of various goods. In the case of prescription drugs, the PPI is a measure of the change in prices exacted by drug manufacturers for the prescription drugs they sell. Between 1981 and 1986, the annual growth rate in the PPI for prescription drugs was 10.1 percent. In 1987 and 1988, the PPI increased 9.6 percent and 7.9, respectively.

The Consumer Price Index (CPI) is a widely used measure of inflation in the consumer economy. During the 1970's, the CPI for prescription drugs grew very slowly, much more slowly than the CPI for all items. During the 1980's, however, the CPI for

prescription drugs grew very rapidly, the CPI for all items. For example, the average annual growth rate in the CPI 10.2 percent, while the average annual for all items was 4.2 percent. This trend in 1987 and 1988, with the CPI for prescription drugs at 8.0 percent and 7.8 percent, respectively. The CPI for drugs has kept pace with the PPI essentially, pharmacists have not increased prices more than what was necessary to keep pace with the cost of purchasing drugs.

In light of the financial difficulty facing the program, we are looking with a cautious eye at the CPI and PPI for prescription drugs. We are aware that, since 1980, the CPI for prescription drugs has increased more rapidly than any other component of the CPI -- including physician services. The drug program has the potential to be a volatile program.

I should point out at this time that the drug benefit for the drug benefit is extremely tight. The January 1, 1991 will require the timely completion of critical tasks both inside and outside the Department, the most important of which is the procurement of drugs. The full cooperation of all departments is necessary in order to accomplish what is, by any measure, a difficult procurement. There is virtually no tolerance for delay in this process. Any delay in this process will make it impossible to meet the legislatively required timeframe extremely.

CONCLUSION

In concluding my statement, I would not like to say that the outpatient prescription drug benefit reform is the Medicare program, and is laden with administrative challenges. As we forge ahead with implementation, on schedule, we are confronting the underfunding of the drug trust fund and the increase in prescription drug prices in recent years. Working with this Committee and others, we will ensure that the drug program is financially sound and that beneficiaries are well served.

prescription drugs grew very rapidly, far outpacing the growth in the CPI for all items. For example, between 1981 and 1986, the average annual growth rate in the CPI for prescription drugs was 10.2 percent, while the average annual percent change in the CPI for all items was 4.2 percent. This trend moderated slightly in 1987 and 1988, with the CPI for prescription drugs increasing by 8.0 percent and 7.8 percent, respectively, in those years. The CPI for drugs has kept pace with the PPI rather consistently -- essentially, pharmacists have not increased their prices more than what was necessary to keep pace with their increasing costs of purchasing drugs.

In light of the financial difficulty facing the drug trust fund, we are looking with a cautious eye at the very rapid growth in the CPI and PPI for prescription drugs since 1981. We are also aware that, since 1980, the CPI for prescription drugs has risen more rapidly than any other component of the CPI for medical items -- including physician services. Clearly, the drug benefit has the potential to be a volatile program.

I should point out at this time that the implementation schedule for the drug benefit is extremely tight. Implementation on January 1, 1991 will require the timely execution of a number of critical tasks both inside and outside the Department, most important of which is the procurement of the drug bill processors. The full cooperation of all parties will be required in order to accomplish what is, by any measure, a very complex procurement. There is virtually no tolerance in this schedule. Any delay in this process will make implementation within the legislatively required timeframe extremely difficult to achieve.

CONCLUSION

In concluding my statement, I would note that the catastrophic outpatient prescription drug benefit represents a major expansion of the Medicare program, and is laden with enormous administrative challenges. As we forge ahead with implementation, on schedule, we are concerned by the projected underfunding of the drug trust fund and the volatility of prescription drug prices in recent years. We look forward to working with this Committee and others to help ensure that the drug program is financially sound and that it serves Medicare beneficiaries well.

The CHAIRMAN. Mr. Hays, you started off and ended your statement talking about the underfunding of the Medicare prescription drug program.

Mr. HAYS. Yes, sir.

The CHAIRMAN. Wouldn't we have more funds in that program if we got a better deal for the recipients of those programs? For example, like the VA; they get a pretty good deal for those veterans.

Mr. HAYS. The statutory requirements for drug pricing for the Medicare Program under catastrophic are very specific, and some would argue, quite generous.

The CHAIRMAN. Generous?

Mr. HAYS. Generous in the resulting price that Medicare will be required to pay for prescription drugs.

The CHAIRMAN. Who is the beneficiary of that generosity? Is it the consumer, the taxpayer, the Medicare beneficiary, or the pharmaceutical manufacturers?

Mr. HAYS. Most directly, the retail drug store which is filling the prescription and is the recipient of the amount that Medicare will pay, along with the co-insurance that the beneficiary will pay. Indirectly, I would assume the pharmaceutical industry in general. But the price that Medicare pays is the price that goes directly to the retail pharmacy that is dispensing the prescription for the beneficiary.

The CHAIRMAN. You know, I'm on the Finance Committee. I'm wearing two hats today. And I remember the debate on catastrophic—maybe I was absent that day—but it's beyond me how we allowed, or did not put into the catastrophic insurance legislation an incentive or inducement for Medicare to get the best price. How'd we forget that? What happened to us? Where were you? Why didn't you tell us that we were doing wrong? Everyone else has told us what we did wrong.

[Laughter.]

Mr. HAYS. Well, I was not privy to those discussions.

The CHAIRMAN. You could have slipped a note under the door.

Mr. HAYS. Certainly, I believe that those issues were brought to the attention of the various parties who were considering the legislation.

The CHAIRMAN. You've had some negotiations with the drug manufacturer, Amgen, who's here today. By the way, the only manufacturer who showed up. We're proud of Amgen.

Now, you did some negotiations, I believe, with this company, is that correct?

Mr. HAYS. We spent the better part of a year in discussions with Amgen over their newly approved, product EPO.

The CHAIRMAN. Now, I don't know if you negotiated a good price for the Medicare beneficiaries or a bad price. What do you maintain?

Mr. HAYS. We feel that the price that we have established for the drug is a fair price, both for the Medicare program and for the facilities who will be providing the drug to Medicare patients.

The CHAIRMAN. Now this is a question that's going to show my ignorance of this field. Why could you negotiate with Amgen on this particular drug and not negotiate on other drugs that we purchase through Medicare?

Mr. HAYS. There are a couple pricing mechanism that we have been using until this point has to do with the fact that on January 1, 1991, the full outpatient drug program was implemented for prescription drugs. The particular drug is a somewhat unique situation. It is because of the way in which it is administered for patients that are receiving it, that it is paid for in a somewhat unique fashion. And it is through the end-stage renal disease program that it is paid for.

If we had paid for it under the regular pricing mechanism, the usual reasonable charge method, we would have ended up paying substantial amounts for it.

The CHAIRMAN. Mr. Hays, I thank you.

Now, Mr. Hays, just one or two more questions. I think of the Veterans Administration. It has gotten a good deal for the veterans. The Veterans Administration being appointed care prescription drugs? What's wrong with that?

Mr. HAYS. Well, Mr. Chairman, the question is whether there are so many drugs that the Veterans Administration's system and the way it operates would preclude our taking advantage of that program. The significant difference between the Veterans Administration and the Medicare Program is in the way they are dealing with drugs. The Veterans Administration is in a different situation, I believe, from the Medicare Program. They are dealing with 33 million beneficiaries. They are dealing with their prescriptions through the existing retail pharmacies around the country. That is one thing for the Veterans Administration. For the Medicare Program, the effect is a provider of drugs to go through a network of retail pharmacies. That is a different mechanism as opposed to a delivery system.

Be that as it may, I think that it is a worthwhile pursuing a demonstration of that sort. But I would point out to you that authority.

The CHAIRMAN. Well, the law could be changed. And that's again what we are looking at. But we are going to do something, and I hope he didn't consider that a threat, it was just a fact that we're going to do something about Catastrophic. I don't know what to do something. I wish I knew. And about the escalating costs of drugs. I don't know how to react to that. And I hope that we are in the right way.

Mr. HAYS. There are a couple of reasons, Mr. Chairman. The pricing mechanism that we have been talking about principally up until this point has to do with the benefit that becomes effective on January 1, 1991, the full outpatient prescription drug benefit. We do not, as you know, today, under Medicare pay for outpatient prescription drugs. The particular drug in question, involving Amgen, is a somewhat unique situation. It is covered under Medicare because of the way in which it is administered in renal dialysis facilities for patients that are receiving kidney dialysis. And we are paying for it as an adjunct to the end-stage renal disease program in a somewhat unique fashion. And it is because we are paying for it through the end-stage renal disease program that we were able to pay for it.

If we had paid for it under the regular Medicare Program following the usual reasonable charge methodology, we would undoubtedly have ended up paying substantially more for this drug.

The CHAIRMAN. Mr. Hays, I thank you.

Now, Mr. Hays, just one or two more questions. What would you think of the Veterans Administration being appointed? They seem to have gotten a good deal for the veterans. What about the Veterans Administration being appointed to do all the buying for Medicare prescription drugs? What's wrong with that?

Mr. HAYS. Well, Mr. Chairman, I think that the threshold question is whether there are so many differences between the Veterans Administration's system and the Medicare Program that they would preclude our taking advantage of the Veterans Administration program. The significant difference, of course, is the fact that the Veterans Administration is in the position of actually providing drugs directly to their beneficiaries, the veterans. It's quite a different situation, I believe, from the Medicare Program where we are dealing with 33 million beneficiaries who will be obtaining their prescriptions through the existing network of 55,000 or 60,000 retail pharmacies around the country. And I guess I would submit that it is one thing for the Veterans Administration, which is in effect a provider of drugs to go through their process, and another thing for the Medicare Program which is primarily a financing mechanism as opposed to a delivery mechanism to do the same.

Be that as it may, I think that it is certainly worth looking at. It may be worthwhile pursuing a demonstration project, or something of that sort. But I would point out that current law does not give us that authority.

The CHAIRMAN. Well, the law could be changed, if it would be a constructive change. And that's again what the Aging Committee is looking at. But we are going to do something, as I told Mr. Moisinghoff, and I hope he didn't consider this a threat. It was not a threat, it was just a fact that we're going to do something. This institution, this Congress is going to do something. We're going to do something about Catastrophic. I don't know what, but we're going to do something. I wish I knew. And we're going to do something about the escalating costs of drugs. I mean, this institution is going to react to that. And I hope that we don't overreact. I hope we act in the right way.

I'm all supportive of some of the things that the pharmaceutical manufacturers have done. I'm very critical of others. And I've stated those criticisms today.

Mr. HAYS. We certainly wish you well and we would be pleased to cooperate with your staff—

The CHAIRMAN. I'm also believing that we can get a better price, Mr. Hays, for those prescription drugs we are today buying for the Medicare beneficiaries. We can do it. And I thank you very, very much for coming.

Mr. HAYS. Thank you very much, Mr. Chairman.

The CHAIRMAN. Now, I have a final witness this morning. That is George Rathmann, chairman of the board, Amgen Inc., Thousand Oaks, CA.

Mr. Rathmann, you have been a patient man. You have sat here for hours listening to all of this. I don't know if you heard anything new. I heard some things that I certainly didn't know before. During the process of preparing for this hearing, I learned a lot, and I hope that we can put these suggestions to constructive use. We look forward to your statement.

STATEMENT OF GEORGE B. RATHMANN, CHAIRMAN OF THE BOARD, AMGEN INC., THOUSAND OAKS, CA

Mr. RATHMANN. Thank you. The statement that's been submitted also includes a Business Week survey on research and development funding in which Amgen ranks first in terms of dollars spent per employee and as a percent of sales.

The CHAIRMAN. We laud you for being the only manufacturer that we invited who came. You came all the way from California and we are very indebted.

Mr. RATHMANN. Well, I think I can explain that, and it's a credit to the industry as well as us that we're here.

We are the newest biopharmaceutical company. Our first product went on the market, just a month ago. The biopharmaceutical industry only has two companies that presently market products, and we're the second. The industry is very promising; it could continue to expand the pharmaceutical advantage the United States has. As of now, there are only two biopharmaceutical companies based on advanced biotechnology, specifically genetic engineering to make new rationally designed drugs.

Now there are really two reasons why we're here. And one is that we really feel we have a role in helping the public and the Congress to understand this industry. And, as a matter of fact, helping the Pharmaceutical Manufacturers Association, of which we are research affiliates, explain this industry to the Congress and to the public. In a moment I'll explain why. The second reason is that we have held discussions with the Health Care Financing Administration for over a year, and in many respects that's an experience that has not occurred before. There are also some specific reasons for this and we must be careful not to generalize, obviously, and we'll help to share what we know about that relationship with you.

First I'd like to address why we can help in this process. First of all, we have only one product. The investments that have been

made in our company are public. Our sales curves will relate to the product is introduced, hopefully so the information is tied together in be interpreted from public data. The only issue we might have is we're apt to see in sales 2 or 3 years do, but other than that our information there's no reason not to help you in the best possible way. And it does give process of creating a new pharmaceutical.

By the way, ours is a 1-A drug, value. Our next one will probably those drugs that represents a new tant therapeutic gain, recognized by

The CHAIRMAN. Now, how many market last year?

Mr. RATHMANN. On the average and three of such drugs.

The CHAIRMAN. Of course, this through, is this correct?

Mr. RATHMANN. We're careful about

The CHAIRMAN. You hope that it

Mr. RATHMANN. OK.

Now, if we turn to the discussion Care Financing Administration, we those discussions because we felt they needed, and were prepared to share special circumstance because of the environment. This particular drug, which will elicit year, is tied primarily to that end

As a result of that, it was clear the standing of the price tag for this ground information I just disclosed cost of those investments were, how our company has been in business product. So the investment is extremely allocate a portion of our investment comes out to be substantially higher been used here today. But it is a break

Now, there are a number of questions about what kinds of discussions with the Financing Administration. It was true of information. They told us some ways of measuring. They requested about what cost savings would be would be the benefits to the quality a thorough analysis over that year formation done both by our own study had a measure of just how valuable They had an opportunity to see the drug, physicians, leading world figure importance of this drug, as well as data. And the Medicare people also